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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,686	11/03/2006	Charles Lowenstein	07410010AA	2022

30743 7590 06/29/2010

WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C.
11491 SUNSET HILLS ROAD
SUITE 340
RESTON, VA 20190

EXAMINER	
SALIMI, ALI REZA	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
06/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,686	LOWENSTEIN ET AL.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *7-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/31/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-6 and within the scope of elected SEQ ID NO: 8) in the reply filed on 01/04/2008 is acknowledged.

Claims 7-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups. Election was made **without** traverse in the reply filed on 01/04/2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since the intended metes and bounds of the fusion protein is not defined. The first and second sequences have not been defined. What are the proteins that promote translocation or inhibit NSF? This affects dependent claims.

Claim 4 is indefinite for recitation of open language "comprising" since the intended boundaries are not defined. According to the disclosure only certain fragment mange to down regulate NSF, yet the claim refers to an unlimited number of proteins.

Claim Rejections - 35 USC § 112

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for fusion protein of TNF-NSF700 (SEQ ID NO:8) to be able to reduce the activity of NSF, does not reasonably provide enablement for any and all types of fusion protein to inhibit the activity of NSF factor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. As Applicants' own disclosure attests the filed of down regulation of inflammation is rather complex and unpredictable. One of ordinary skill in the art would be forced to conduct large quantity of undue experimentation to enable the full scope of the claimed invention.

The disclosure's own teaching indicates that not all of the fusion proteins down inhibited or even down regulated the activity of NSF (For example see Figures 8 or 10). Yet the claims are directed to myriad of fusion protein of all shapes and sizes to inhibit the activity of NSF.

This means the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. See In re Wright, 999 F.2d 1557,1562, 27USPQ2d 1510, 1513 (Fed. Cir. 1993).

Additionally regarding an unpredictable field, the current disclosure does not constitute an adequate disclosure. See See Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir.

1993); and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk, 108 F.3d 1361, 42 USPQ2d 1001 (Fed.Cir. 1997). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). In the instant case the specification does not teach or provide any guidance for any and all fusion protein to inhibit NSF. And the disclosure must adequately guide the art worker to determine, without undue experimentation. Applicants cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized in, In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. In the instant disclosure, Applicants have only disclosed the sequence consisting of and identified as SEQ ID NO: 8 which can downgrade the activity of NSF activity.

Thus, Applicants have provided only one specie but the scope of the claims read on broad genus of fusion proteins. The disclosure fails to describe representative number of species falling within the scope of the genus or provide structural features common to members of the genus so one of skill in the art can "visualize or recognize" the members of genus. See University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997)

No other sequences were disclosed. The specification does not set forth the metes and bounds of what's being claimed and there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed homologous regions or its variation thereof. Therefore, a written description of the other claimed sequences should be disclosed to overcome this rejection. See also Eli Lilly which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 19 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Additionally, the specification as filed fails the standard of written description. Applicants have provided a wish list and the disclosure fails to provide adequate teaching under the quid pro quo doctrine.

The goal of written description requirement is "to clearly convey the information that an applicant has invented the subject matter which is claimed", see In re Barker, 559 F.2d 588, 592 n.4 (CCPA 1977). The inventor has an obligation under "written description" to disclose the technologic knowledge upon which the patent is based and to demonstrate that the patentee was in possession of the invention that is claimed. See Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005). In the instant disclosure, Applicants have made broad statements and more or less a

wish list for others to conduct research. Applicant cannot enjoy the fruit of excluding others from practicing the invention for a limited period of time without providing the public meaningful disclosure. Ariad Pharmaceuticals Inc. v. Eli Lilly & Co., 94 USPQ2d 1161 (Fed. Cir. 2010) (en banc). It's noted that Applicants have added a functional language of "promotes translocation… that inhibits … "NSF" activity" in claim 1 to delineate possession. As the holding in Ariad indicated, however, the employment of such functional language does not relive Applicants to fully comply with obligation in satisfying written disclosure. The Court reasoned: "drawing a fence around the outer limits of purported genus is not adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species", Id.

Here, Applicants' teachings do not commensurate with the scope of patent protection. Applicants were not in possession of multitude of fusion proteins that promote translocation and inhibit NSF activity. The disclosure does not possess what it claims. The specification does not set forth the metes and bounds of that encompass, and there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed regions where the region may encompass. Thus, the disclosure fails to provide a meaningful disclosure and possession of the broad scope of the now claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Blanes-Mira et al (Society for Neuroscience Abstracts, 2001, Vol. 27, No. 1, pp. 1017).

The above cited abstract taught a fusion protein of TAT sequence which promotes translocation and SNAP-25 N-terminus as a second sequence which inhibits the NSF activity and regulated endothelial exocytosis (see the entire abstract).

The product as taught by above cited art clearly anticipates the broad limitations of the now claimed invention. Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Subject Matter Free of Prior art

Claim 5 is deemed free of prior art, given failure of the prior art to teach or reasonably suggest the SEQ ID NO: 8 as a fusion of TAT and D2 domain of NSF wherein the protein down regulates NSF activity.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/A R Salimi/
Primary Examiner, Art Unit 1648

06/24/2010